Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of two anesthetics methods of Inferior Alveolar Nerve Block and crestal anesthesia and two anesthetics materials of lidocaine and articaine in the crestal anesthesia for pulpotomy treatment of primary molars

Protocol summary

Study aim

Determination and comparison of local anesthesia of inferior alveolar nerve block (IANB) and crystal anesthesia (CA) in the treatment of pulpotomy of mammary molars Determining and comparing the use of lidocaine and articaine anesthetics in crystal anesthesia (CA) in the treatment of mammary pulpotomy

Design

Clinical trial. With parallel groups. One-way blind. Randomized. Phase 2 on 90 patients. To randomize the Crossover plan will be done in 2 separate sessions at least one week apart

Settings and conduct

In the pediatric dentistry department, pulpotomy of 2 teeth will be performed during 2 facial sessions in 45 children with block anesthesia and in the post-crystal anesthesia session. In another 45 children, a local anesthesia session will be performed with lidocaine and the next session with articaine.Data analyzer compared to blinded study.

Participants/Inclusion and exclusion criteria

Inclusion criteria include: 1- Children who need a bilateral pulpotomy of deciduous molars (D or E) in the mandible based on clinical signs and radiography and at the diagnosis of a pediatric dentist. 2- Age category 4 to 8 years 3- Parents' consent to partiExclusion criteria include: 1- Having a history of systemic disease 2- Having severe fear and anxiety 3- Using painkillers to control toothache 4- Having acute dental infections 5- Having deciduous molars that have more than two thirds of their roots decayedcipate in the study

Intervention groups

Pulpotomy of 2 teeth will be done in 2 sessions; In 45 children, one session of local anesthesia will be performed on the inferior alveolar nerve block (IANB) and in the other session, crystal anesthesia (CA) will be performed, and in 45 children, one session of local anesthesia will be performed with lidocaine and the next session with articaine.

Main outcome variables

Pain during pulpotomy treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171020036896N9**
Registration date: **2021-06-05, 1400/03/15**
Registration timing: **registered_while_recruiting**

Last update: **2021-06-05, 1400/03/15**
Update count: **0**

Registration date

2021-06-05, 1400/03/15

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 32119023

Email address

sajadi@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-04-20, 1400/01/31

Expected recruitment end date

2021-08-21, 1400/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two anesthetics methods of Inferior Alveolar Nerve Block and crestal anesthesia and two anesthetics materials of lidocaine and articaine in the crestal anesthesia for pulpotomy treatment of primary molars

Public title

Clinical success and pain of two anesthetics methods of Inferior Alveolar Nerve Block and crestal anesthesia and two anesthetics materials of lidocaine and articaine in the crestal anesthesia for pulpotomy treatment of primary molars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children who need a bilateral pulpotomy of deciduous molars (D or E) in the mandible based on clinical signs and radiography and at the diagnosis of a pediatric dentist. Age category 4 to 8 years Parents' consent to participate in the study

Exclusion criteria:

Having a history of systemic disease Having severe fear and anxiety Using painkillers to control toothache Having acute dental infections Having deciduous molars that have more than two thirds of their roots analyzed

Age

From **4 years** old to **8 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **2**

Pulpotomy of 2 teeth will be done in 2 sessions

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the simple randomization method (flip the coin) will be used. In such a way that one of the study groups will be considered as heads and the other group will be considered as tails. Then the same number of coins will be thrown based on the sample size. Finally, to prevent disclosure of random sequencing, the allocation concealment will be used

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of local anesthetic agent and technique at the time of treatment. Statistics consultant is not aware of local anesthetic agent and technique at the time of treatment too.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kerman University of Medical Sciences

Street address

shafa street

City

kerman

Province

Kerman

Postal code

7618759689

Approval date

2021-03-01, 1399/12/11

Ethics committee reference number

IR.KMU.REC.1399.645

Health conditions studied

1

Description of health condition studied

The comparison of effect of inferior alveolar nerve block and crestal local anesthesiain in pulpotomy of primary teeth

ICD-10 code

ICD-10 code description

2

Description of health condition studied

The effect of crestal local anesthesia using lidocaine in pulpotomy of primary teeth

ICD-10 code

ICD-10 code description

3

Description of health condition studied

The effect of crestal local anesthesia using articaine in pulpotomy of primary teeth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
pain
Timepoint
Immediately after the crestal injection, the child's pain is measured by the VAS (Visual Analogue Scale) during the opening of the dental pulp.
Method of measurement
The child's pain is measured by the VAS (Visual Analogue Scale).

2

Description
Changes in the heart rate to determine the amount of pain experienced by the child during the crestal injection.
Timepoint
Changes in a child's heart rate are made by using a pulse oximeter 5 seconds before and immediately after the local anesthetic injection.
Method of measurement
Changes in a child's heart rate are made by using a pulse oximeter 5 seconds before and immediately after the local anesthetic injection.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: In this group, in the first session, pulpotomy of a mandibular primary molar will be performed by injecting inferior alveolar nerve block using lidocaine 2% with epinephrine 1: 100,000 (produced by Iran Pharmaceutical Company) and in the second session, pulpotomy of a primary molar will be performed on the other side of the mandible by crestal local injection using lidocaine 2% with epinephrine 1: 100000 (produced by Iran Pharmaceutical Company). Before and after the local anesthetic injection, changes in the child's pulse is measured using a pulse oximeter in both sessions. After an appropriate time (10 minutes) to determine the time of onset of anesthesia, IANB anesthesia is tested with a catheter after the child's lip feels numb, and CA anesthesia is tested immediately after injection into the second papilla. Then the caries removal process and preparation of the access cavity begin and the child's reaction is measured at the moment of pulp exposure. Before the treatment, the assistant will explain the Visual Analogue Scale (VAS) to the child and how to display the amount of discomfort on it, and immediately while preparing the access cavity in dentin or in case of need for pulp treatment at the time of pulp exposure. The child is asked to rate one of the smileys from zero (painless) to 10 (unbearable pain) based on the intensity of the pain he feels. The result is then recorded on the child form.
Category
Treatment - Drugs

2

Description
Intervention group 2: In this group, in the first session, pulpotomy of a mandibular primary molar will be performed by crestal local injection using lidocaine 2% with epinephrine 1: 100,000 (produced by Iran Pharmaceutical Company) and in the second session, pulpotomy of a primary molar will be performed on the other side of the mandible by crestal local injection using articaine 4% with epinephrine 1: 100000 (produced by Iran Pharmaceutical Company). Before and after the local anesthetic injection, changes in the child's pulse is measured using a pulse oximeter in both sessions. To determine the time of onset of anesthesia, CA anesthesia is tested immediately after injection into the second papilla. Then the caries removal process and preparation of the access cavity begin and the child's reaction is measured at the moment of pulp exposure. Before the treatment, the assistant will explain the Visual Analogue Scale (VAS) to the child and how to display the amount of discomfort on it, and immediately while preparing the access cavity in dentin or in case of need for pulp treatment at the time of pulp exposure. The child is asked to rate one of the smileys from zero (painless) to 10 (unbearable pain) based on the intensity of the pain he feels. The result is then recorded on the child form.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of Dentistry
Full name of responsible person
Parisa Jafari
Street address
Shafa Ave
City
Kerman
Province
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Postal code
7618759689
Phone
+98 34 8074 3211
Email
Parisajafaridnt@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Abbas Pardakhti

Street address
Shafa Ave

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7618759689

Phone
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Parisajafaridnt@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Kerman University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Parisa Jafari

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Shafa Ave

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7618759689

Phone
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Email
Parisajafaridnt@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Parisa Jafari

Position
Resident

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Parisa Jafari

Position
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Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available